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RESEARCH**

*APPLICATION NUMBER:*

**75-189**

**CHEMISTRY REVIEW(S)**

**Office of Generic Drugs**  
**Chemistry, Manufacturing and Controls Review**

1. CHEMIST'S REVIEW NO: No. 4
2. ANDA: 75-189 [Nabumetone Tablets, 500 mg and 750 mg]
3. NAME AND ADDRESS OF APPLICANT:  
Teva Pharmaceuticals USA  
Attention: Deborah A. Jaskot  
650 Cathill Road, Sellersville, PA 18960
4. LEGAL BASIS for ANDA SUBMISSION: See CR #1
5. SUPPLEMENT(s): N/A
6. PROPRIETARY NAME: N/A
7. NONPROPRIETARY NAME: Nabumetone Tablets, 500 mg and 750 mg
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:  
TEVA:  
08/18/97 Submission of ANDA (received on 08/25/97)  
10/08/97 Correspondence (Re: U.S. Patent)  
10/23/97 Correspondence (Re: U.S. Patent)  
12/16/97 Correspondence (Re: U.S. Patent)  
12/17/97 Submission of bio chromatograms  
01/07/98 Correspondence from law firm (Re: legal action)  
04/28/98 Amendment (in response to CMC/labeling and bio letters)  
11/23/98 Facsimile amendment (in response to 09/22 & 11/03 letter)  
02/03/99 SSCBE (PAC-ATLS) (additional testing sites)  
02/09/99 Gratuitous amendment (additional testing sites)  
03/04/99 Withdrawal of Gratuitous amendment dated 02/09/99  
01/11/00 Minor amendment  
02/22/00 Telephone amendment  
05/01/00 \*Amendment (Re: revised FPL)  
  
FDA:  
10/01/97 Acknowledgment letter  
12/01/97 Ms. Sanchez (OGD) requested bio data by phone.  
02/09/98 Bioequivalence letter (Re: dissolution)  
02/25/98 NA (MAJOR) (CMC deficiencies based on CR #1 by Liu)  
09/22/98 Bio letter (dated 08/06/98) faxed to Teva  
11/03/98 NA (Facsimile) (CMC deficiencies based on CR #2 by Liu)  
12/24/98 Tentative approval letter  
02/08/99 Telephone conversation (M. Anderson to D.Jaskot)  
02/10/00 Telephone amendment request (re: MV issue)
10. PHARMACOLOGICAL CATEGORY: Anti-inflammatory
11. HOW DISPENSED: Rx
12. RELATED IND/NDA/DMF(s): See CR #1 for details
13. DOSAGE FORM: Oral Tablets

14. **Strength:** 500 mg and 750 mg

15. **CHEMICAL NAMES AND STRUCTURE:**

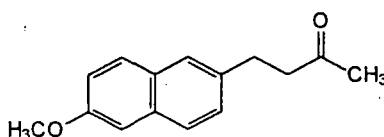
Generic name: Nabumetone

Chemical name: 2-Butanone, 4-(6-methoxy-2 naphthalenyl)-

Formula: C<sub>15</sub>H<sub>16</sub>O, Molecular weight: 228.29

CAS registry number(s): 42924-53-8

Chemical structure:



16. **RECORDS AND REPORTS:** N/A

17. **COMMENTS:**

Both the bulk drug substance and the drug product still do not have USP monographs.

The DMF of the drug substance is adequate as of this review. The CMC issue on method validation was resolved in the last chemistry review. There has been no other CMC issues.

Teva submitted an amendment on Labeling, which was reviewed by labeling reviewer on 05/04/00. Labeling approval summary was signed off on 05/05/00.

EER was acceptable on 09/22/98.

18. **CONCLUSIONS AND RECOMMENDATIONS:**

Approvable

19. **REVIEWER:** Shing H. Liu, Ph.D. **DATE COMPLETED:** 05/09/00

Page(s)

7

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Commercial/Confidential

Information and are not  
releasable.

Chem Rev 4

5/9/00